B. A. I. Order 276. Issued October 10, 1922.

UNITED STATES DEPARTMENT OF AGRICULTURE.

Bureau of Animal Industry.

JOHN R. MOHLER, Chief of Bureau.

REGULATIONS GOVERNING THE PREPARATION, SALE, BARTER, EXCHANGE, SHIPMENT, AND IMPORTATION OF VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS INTENDED FOR USE IN THE TREATMENT OF DOMESTIC ANIMALS.

Effective on and after November 1, 1922.

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U. S. Department of Agriculture,
Office of the Secretary,
Washington, D. C., August 18, 1922.

Under authority of the act of Congress approved March 4, 1913, entitled "An act making appropriations for the Department of Agriculture for the fiscal year ending June 30, 1914" (37 Stat. 832), the following regulations are hereby issued for the purpose of enforcing the provisions of said act governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals. These regulations, which for the purpose of identification are designated as B. A. I. Order 276, shall become and be effective on and after November 1, 1922, except that any establishment may until December 31, 1922, continue to use the phrase "U. S. Released" on its products in the manner provided for the use thereof in B. A. I. Order 265.

Henry C. Wallace,
Secretary of Agriculture.

8177—22——1

REGULATION 1.—DEFINITIONS.

SECTION 1. *Paragraph 1.* For the purpose of these regulations, the following words, phrases, names, and terms shall be construed, respectively, to mean:

Paragraph 2. The virus-serum-toxin act of 1913: "An act making appropriations for the Department of Agriculture for the fiscal year ending June 30, 1914," approved March 4, 1913 (37 Stat. 832).

Paragraph 3. Viruses, serums, toxins, and analogous products, or veterinary biologics: All viruses, serums, toxins, and analogous products, such as antitoxins, vaccines, tuberculins, malleins, live microorganisms, killed microorganisms, or bacterins, and products of microorganisms which are intended for use in the treatment of domestic animals.

Paragraph 4. The department: The United States Department of Agriculture.

Paragraph 5. The bureau: The Bureau of Animal Industry of the United States Department of Agriculture.

Paragraph 6. Bureau employee: Any officer, agent, or other individual employed in the Bureau of Animal Industry who is authorized by the chief of the bureau to do any work or perform any duty in connection with the execution of the provisions of the virus-serum-toxin act of 1913.

Paragraph 7. Veterinary inspector: A veterinary inspector of the Bureau of Animal Industry.

Paragraph 8. Lay inspector: A lay inspector of the Bureau of Animal Industry.

Paragraph 9. Licensed establishment: Any establishment owned or operated by a person, firm, or corporation holding an unexpired, unsuspended, and unrevoked license issued by the Secretary of Agriculture for the preparation of any virus, serum, toxin, or analogous product.

Paragraph 10. Official station: One or more licensed establishments included under a single supervision.

Paragraph 11. Inspector in charge: An inspector assigned to supervise and perform official work at an official station and who reports directly to the chief of the bureau.

Paragraph 12. Person: Natural persons, individuals, firms, partnerships, corporations, companies, societies, and associations and every agent, officer, or employee of any thereof. This term shall import both the plural and the singular, as the case may be.

Paragraph 13. Hog-cholera virus: The clear serum, plasma, or defibrinated blood derived from pigs sick of hog cholera and free from other communicable disease or diseases.

Paragraph 14. Hyperimmunizing virus: Hog-cholera virus prepared for hyperimmunizing hogs which are immune to hog cholera.

Paragraph 15. Simultaneous virus: Hog-cholera virus prepared for inoculating hogs which are to be injected simultaneously with anti-hog-cholera serum for the immunization of those animals against hog cholera.

Paragraph 16. Anti-hog-cholera serum: The clear serum, plasma, or defibrinated blood, or derivatives thereof, containing the protective principles derived from immune hogs which have been hyperim-

munized by an intravenous injection of at least 5 cubic centimeters, per pound body weight, of the virus of hog cholera.

Paragraph 17. Immediate or true container: The unit, bottle, vial, ampul, tube, or other receptacle, or container in which any virus, serum, toxin, or analogous product is customarily sold or distributed.

Paragraph 18. Serial number: The number given each batch of virus, serum, toxin, or analogous product to identify the said virus, serum, toxin, or analogous product with the records of preparation thereof.

Paragraph 19. Return date: The date placed upon trade labels affixed to or used in connection with immediate or true containers of viruses, serums, toxins, and analogous products by producers to indicate the limit of time during which the said products may be expected to retain their full strength or potency.

Paragraph 20. U. S. Released: That veterinary biologics so marked have been prepared and tested in accordance with the provisions of these regulations and that when thus prepared, tested, and marked, they were not found to be worthless, contaminated, dangerous, or harmful.

REGULATION 2.—LICENSES AND INSPECTIONS.

SECTION 1. Every establishment in the United States at which any virus, serum, toxin, or analogous product is prepared for sale, barter, or exchange in the District of Columbia or in any Territory of or place under the jurisdiction of the United States, or for shipment or delivery for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, shall hold an unexpired, unsuspended, and unrevoked license, issued by the Secretary of Agriculture, and shall have inspection under these regulations.

SECTION 2. All viruses, serums, toxins, and analogous products produced at licensed establishments shall be prepared, handled, stored, marked, received for transportation, and transported as required by these regulations.

SECTION 3. *Paragraph 1.* The proprietor or operator of each establishment of the kind specified in section 1 of this regulation shall make application in writing to the Secretary of Agriculture for a license. When one proprietor conducts more than one establishment, a separate application shall be made for a license for each establishment. Blank forms of application will be furnished upon request addressed to the Bureau of Animal Industry, Washington, D. C.

Paragraph 2. Triplicate copies of plans, properly drawn to scale, and of specifications, including plumbing and drainage of establishments, together with triplicate copies of all labels and advertising matter to be used in connection with or relating to all viruses, serums, toxins, and analogous products prepared therein, shall accompany the application for a license, unless these plans, specifications, labels, and advertising matter have already been approved in writing by the bureau.

Paragraph 3. In case of change in ownership or location while an application is pending, or after a license has been issued, a new application shall be made.

SECTION 4. *Paragraph 1.* A license will not be issued unless the condition of the establishment and the methods of preparation are such as reasonably to insure that the products will accomplish the object for which they are intended and that they are not worthless, contaminated, dangerous, or harmful.

Paragraph 2. A license will not be issued unless and until the establishment is prepared to operate under the direct supervision of a competent person trained in bacteriological technic or in the preparation of viruses, serums, toxins, or analogous products named in the application.

Paragraph 3. A license will not be issued for the preparation of any virus, serum, toxin, or analogous product if advertised so as to mislead or deceive the purchaser, or if the package or container in which the same is intended to be sold, bartered, exchanged, or shipped bears or contains any statement, design, or device which is false or misleading in any particular.

SECTION 5. *Paragraph 1.* A license will be issued only after inspection of the establishment by a bureau employee has shown that the condition and equipment of the establishment and the methods of preparing, handling, and storing products are in conformity with these regulations.

Paragraph 2. Licenses shall be numbered and shall be in the following form:

UNITED STATES VETERINARY LICENSE NO. ———.

WASHINGTON, D. C.,_____, 19___

This is to certify that, pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, _____ is hereby licensed to maintain at_____an establishment for the preparation of_____.

This license is subject to termination as provided in the regulations made under the authority contained in said act approved March 4, 1913, and also to suspension or revocation if the licensee violates or fails to comply with any provision of the said act or the regulations made thereunder.

_____,
Secretary of Agriculture.

Countersigned:

_____,
Chief, Bureau of Animal Industry.

Paragraph 3. Two or more licenses may bear the same number when they are issued to firms under the same ownership or control, provided a serial letter is added when necessary, to identify each license.

Paragraph 4. Should a licensed establishment discontinue the production of any virus, serum, toxin, or analogous product, the license of such establishment shall be returned to the bureau for termination and a new license issued covering such products named therein as the establishment shall continue to produce. Should an establishment be engaged in the preparation of products under a number of licenses issued from time to time by the department, the licenses shall be returned to the bureau at its request for termination and a new license issued covering all the products embraced in the returned licenses which the establishment shall continue to produce.

SECTION 6. *Paragraph 1.* No viruses, serums, toxins, or analogous products shall be prepared in whole or in part in a licensed establishment by any other licensed establishment unless authorized in advance by the chief of bureau.

Paragraph 2. Each licensed establishment shall be separate and distinct from any unlicensed establishment in which any virus, serum, toxin, or analogous product is prepared or handled.

Paragraph 3. When a license is issued the bureau shall inform the proprietor or operator of the establishment of the requirements of these regulations. If the establishment, at the time the license is issued, has in possession any viruses, serums, toxins, or analogous products, which have not theretofore been prepared and of which the containers have not been theretofore marked in compliance with these regulations, the identity of the same shall be maintained and they shall not be shipped or delivered for shipment from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia, or otherwise dealt with as products prepared under these regulations. The establishment shall adopt and enforce all necessary measures and shall comply with all such directions as the chief of bureau may prescribe for carrying out the purposes of this paragraph.

REGULATION 3.—PERMITS.

SECTION 1. Each importer of viruses, serums, toxins, or analogous products shall hold an unexpired, unsuspended, and unrevoked permit issued by the Secretary of Agriculture.

SECTION 2. *Paragraph 1.* Each importer of viruses, serums, toxins, and analogous products shall make application in writing to the Secretary of Agriculture for a permit. The application shall specify the port or ports of entry at which the imported articles will be cleared through the customs. Blank forms of application will be furnished upon request addressed to the Bureau of Animal Industry, Washington, D. C.

Paragraph 2. Each application for a permit shall be accompanied by the affidavit of the actual manufacturer produced before an American consular officer, giving the city or town where the viruses, serums, toxins, or analogous products mentioned therein are prepared, and stating that said products are not worthless, contaminated, dangerous, or harmful; whether the products were derived from animals, and, if so derived, the name of the species, and that such animals have not been exposed to any infectious or contagious disease, except as may have been essential in the preparation of the products and as specified in the affidavit.

Paragraph 3. Each application for a permit shall be accompanied by the written consent of the actual manufacturer that properly accredited employees of the department shall have the privilege of inspecting, without previous notification, all parts of the establishment at which such viruses, serums, toxins, or analogous products are prepared, and all processes of and all records kept relative to the preparation of such products at such times as may be demanded by the aforesaid employees.

Paragraph 4. Each application for permit shall be accompanied by triplicate copies of all labels and advertising matter.

SECTION 3. A permit will not be issued for the importation of any viruses, serums, toxins, or analogous products if advertised so as to mislead or deceive the purchaser, or if the package or container in which the same is intended to be sold, bartered, exchanged, shipped, or imported bears or contains any statement, design, or device which is false or misleading in any particular.

SECTION 4. *Paragraph 1.* Permits shall be numbered and shall be in the following form:

UNITED STATES VETERINARY PERMIT NO. ------

WASHINGTON, D. C., _____, 19___

This is to certify that, pursuant to the terms of the act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, _____, State of _____, is hereby authorized, so far as the jurisdiction of the Department of Agriculture is concerned, to import_____ manufactured by _____, of _____, into the United States through the port of _____ during the calendar year 19____

This permit is subject to suspension or revocation if the permittee violates or fails to comply with the provisions of the said act approved March 4, 1913, or of the regulations made thereunder.

_____,
Secretary of Agriculture.

Countersigned:

_____,
Chief, Bureau of Animal Industry.

Paragraph 2. Each permit shall terminate at the end of the calendar year for which it is issued.

REGULATION 4.—SUSPENSION OR REVOCATION OF LICENSES AND PERMITS.

SECTION 1. Licenses or permits may be suspended or revoked after opportunity for hearing has been accorded the licensee or permittee if it appears—

(1) That the construction of the establishment in which the viruses, serums, toxins, or analogous products are prepared is defective, or that the establishment is improperly conducted;

(2) That the methods of preparation are faulty, or that the said products contain impurities or lack potency;

(3) That the products are labeled so as to mislead or deceive the purchaser in any particular;

(4) That the license or permit is used to facilitate or effect the preparation, sale, barter, exchange, shipment, or importation of any worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products; or

(5) That the licensee or permittee has violated or failed to comply with any provision of the virus-serum-toxin act of 1913, or of the rules and regulations made thereunder.

SECTION 2. All hearings shall be private and at times and places designated by the Secretary of Agriculture. The parties interested may appear in person or by attorney, and may submit oral or written evidence on the questions involved. Upon request and by paying the cost, the person involved will be furnished with a copy of the transcript of the hearing.

REGULATION 5.—NOTICE TO LICENSEES AND PERMITTEES.

SECTION 1. If at any time it appears that the preparation, sale, barter, exchange, shipment, or importation of any virus, serum, toxin, or analogous product by any person holding a license or permit may be dangerous in the treatment of domestic animals, the Secretary of Agriculture will so notify the licensee or permittee, and unless and until the Secretary of Agriculture shall otherwise direct, no person, so notified, shall thereafter prepare, sell, barter, or exchange, nor shall thereafter ship, offer for shipment, or import any of such product.

REGULATION 6.—ASSIGNMENT OF BUREAU EMPLOYEES.

SECTION 1. Any bureau employee, as defined in these regulations, shall be permitted to enter any establishment licensed under these regulations at any hour during the daytime or nighttime; and such bureau employee shall be permitted to inspect without previous notification the entire premises of the establishment, including all buildings, compartments, and other places, and all equipment, such as chemicals, instruments, apparatus, and the like, as well as the methods used in the manufacture of, and all records maintained relative to, viruses, serums, toxins, or analogous products.

SECTION 2. Each bureau employee, as defined in these regulations, will be furnished with a numbered official badge, which he shall not allow to leave his possession. This badge shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the licensed establishment and premises and to any place at any time for the purpose of making an inspection pursuant to section 1 of this regulation.

REGULATION 7.—FACILITIES FOR INSPECTION.

SECTION 1. When required by the chief of bureau or the inspector in charge, the following facilities, and such others as may be essential to efficient conduct of inspection, shall be furnished by each licensed establishment:

(*a*) Satisfactory pens, equipment, and assistance for conducting tests required in accordance with these regulations.

(*b*) Suitable rooms, compartments, or receptacles in such number and places as may be necessary for holding any viruses, serums, toxins, or analogous products for treatment or testing required in accordance with these regulations. Such rooms, compartments, or receptacles shall be equipped for secure locking and shall be held under locks furnished by the department, and the keys of such locks shall not leave the custody of bureau employees.

(*c*) Suitable containers satisfactorily equipped for thoroughly mixing batches of anti-hog-cholera serum and hog-cholera virus.

(*d*) Thermometers which will register temperatures accurately and satisfactorily for use as required by these regulations.

REGULATION 8.—SANITATION.

SECTION 1. *Paragraph 1.* Triplicate copies of plans properly drawn to scale, and of specifications, including plumbing and drain-

age, for remodeling plants of licensed establishments and for new structures, should be submitted to the chief of bureau in advance of construction.

Paragraph 2. Stables or other premises for animals used in the production of testing of viruses, serums, toxins, or analogous products shall be properly ventilated and lighted, appropriately drained, and guttered, and kept in good sanitary condition.

Paragraph 3. Animals infected with or exposed to any infectious, contagious, or communicable disease shall be properly segregated.

Paragraph 4. Licensed establishments shall be so located as to avoid the spread of disease, and suitable arrangements shall be made for the disposal of all refuse.

Paragraph 5. Direct communication to licensed establishments shall not be maintained from public stockyards, abattoir pens, or other places in which animals are received or held for any purpose.

Paragraph 6. All viruses, serums, toxins, and analogous products shall be prepared, handled, and distributed with due sanitary precautions, and all viruses, serums, toxins, or analogous products shipped or delivered for shipment shall be securely packed.

Section 2. *Paragraph 1.* The floors, walls, ceilings, partitions, posts, doors, and all other parts of all structures at licensed establishments shall be of such material, construction, and finish as can be readily and thoroughly cleaned.

Paragraph 2. Separate rooms or compartments shall be provided for preparing, handling, and storing virulent or attenuated microorganisms or toxins.

Paragraph 3. All rooms and compartments shall have abundant light and sufficient ventilation to insure sanitary and hygienic conditions.

Section 3. *Paragraph 1.* Each licensed establishment shall have dressing rooms and toilet rooms and urinals sufficient in number, ample in size, conveniently located, properly ventilated, and meeting all requirements as to sanitary construction and equipment. These rooms, etc., shall be separate from rooms and compartments in which any viruses, serums, toxins, or analogous products are prepared, handled, or stored.

Paragraph 2. Each licensed establishment shall have modern lavatory accommodations, including running hot and cold water, soap, towels, and the like. These shall be located at such places in establishments as may be essential to assure cleanliness of all persons handling viruses, serums, toxins, or analogous products.

Section 4. There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with approved traps and vents.

Section 5. The water supply, both hot and cold, shall be ample and clean. Adequate facilities shall be provided for the distribution of water in each establishment and for the washing of all equipment, containers, machinery, instruments, other apparatus, and animals used in the preparation, handling or storing of any viruses, serums, toxins, or analogous products.

Section 6. All equipment, containers, instruments, and other apparatus used in the preparation, handling, or storing of any virus, serum, toxin, or analogous product shall be of such material, con-

struction, and design as can be readily and thoroughly cleaned and sterilized, and such equipment, containers, instruments, and other apparatus shall be handled so as to insure freedom from contamination. Equipment, containers, instruments, and other apparatus used for preparing, handling, or storing virulent or attenuated microorganisms or toxins shall not be used for handling, preparing, or storing other forms of biological products.

SECTION 7. All establishment employees who handle viruses, serums, toxins, or analogous products shall keep their hands and clothing clean. The hands of such employees shall not come into contact with any viruses, serums, toxins, or analogous products, or with any part of the equipment, containers, instruments, or other apparatus, which after sterilization may come into contact with any such products.

SECTION 8. Caps, gowns, and other outer clothing worn by persons while handling any viruses, serums, toxins, or analogous products, or by those who enter any room, compartment, or place where any such products are being handled, shall be of clean, white material whenever practicable.

SECTION 9. The outer premises of every licensed establishment, embracing docks, driveways, approaches, yards, pens, chutes, and alleys, shall be drained properly and kept in a clean and orderly condition. The accumulation, on the premises of an establishment, of any material in which flies may breed is forbidden. No nuisance shall be allowed in any licensed establishment or on its premises.

SECTION 10. Every practicable precaution shall be taken to keep establishments free of flies, rats, mice, and other vermin.

SECTION 11. All parts of the carcasses of animals producing viruses, all dead animals, all refuse, and all worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products, shall be incinerated or otherwise destroyed by establishments in accordance with methods approved by the chief of bureau.

SECTION 12. All rooms, compartments, and other places used for preparing, handling, or storing viruses, serums, toxins, or analogous products shall be kept clean and sanitary, and all equipment, containers, instruments and other apparatus used in preparing, handling, or storing any such products shall be thoroughly cleaned and sterilized before use.

SECTION 13. Smoking or expectorating in any room, compartment, or place in which viruses, serums, toxins, or analogous products are prepared, handled, or stored is prohibited.

REGULATION 9.—STERILIZATION.

SECTION 1. *Paragraph 1.* All equipment, containers, instruments, and other apparatus, before being used in preparing, handling, or storing viruses, serums, toxins, or other analogous products, except as prescribed in the following paragraph, shall be thoroughly sterilized by live steam at a temperature of at least 120° C. for not less than one-half hour, or by dry heat at a temperature of at least 160° C. for not less than one hour. If for any reason such methods of sterilization are impracticable, then a process known to be equally efficacious in destroying microorganisms and their spores may be substituted after approval by the chief of bureau.

Paragraph 2. Instruments used in connection with the bleeding of virus pigs and hyperimmune hogs, and other like equipment, of establishments manufacturing hog-cholera virus and anti-hog-cholera serum, which are found to be damaged by exposure to the degree of heat prescribed in the preceding paragraph, after having been thoroughly cleaned may be sterilized by boiling for not less than 15 minutes, provided apparatus satisfactory to the inspector in charge is furnished for this purpose.

Paragraph 3. Licensed establishments shall furnish satisfactory means for insuring that autoclaves and other sterilizers operate efficiently and as required by this regulation. Either efficient automatic temperature-recording gauges or iodid of starch, prepared as approved by the chief of bureau as a temperature indicator, shall be used in the operation of autoclaves and other steam sterilizers. Such gauges likewise shall be attached to dry-heat sterilizers unless they can be and are effectively operated under the direct supervision of a bureau employee while he is engaged on other inspection work requiring his attention. Charts used on these gauges shall be made available at all times for examination by bureau employees.

REGULATION 10.—STORAGE.

SECTION 1. Viruses, serums, toxins, and analogous products which may be injuriously affected by exposure to light or to high temperature shall be stored in a dark, cold chamber or refrigerator at a temperature of not to exceed 55° F. All dealers in the District of Columbia or any Territory or in any place under the jurisdiction of the United States shall keep such products protected from light and under refrigeration until sold or otherwise disposed of.

REGULATION 11.—RECORDS.

SECTION 1. *Paragraph 1.* Permanent detailed records of the sources of the preparation, of tests for purity and potency, and of methods of preservation of each batch of virus, serum, toxin, and analogous products shall be kept by each licensed establishment and by each manufacturer producing such products for importation into the United States.

Paragraph 2. Permanent detailed records in a form satisfactory to the chief of the bureau shall be maintained by each licensed establishment and by each importer, showing the sale, shipment, or other disposition of the viruses, serums, toxins, and analogous products handled.

REGULATION 12.—LABELS.

SECTION 1. *Paragraph 1.* Each immediate or true container of viruses, serums, toxins, or analogous products, prepared for sale, barter, exchange, or shipment by any licensed establishment or importer into the United States, shall bear a trade label as hereinafter described.

Paragraph 2. No container of virus, serum, toxin, or analogous product shall bear a trade label unless and until the product contained therein shall have been prepared in compliance with these regulations and not found to be worthless, contaminated, dangerous, or harmful,

except that containers of antihog-cholera serum and hog-cholera virus prepared as aforesaid may be labeled and marked before the products are released for marketing, provided such labeling and marking are done under the direct supervision of a bureau employee and the products immediately thereafter placed under bureau lock, where they will be held until released for marketing. No person shall have access to the compartment in which such labeled or marked products are held under lock except in the immediate presence of a bureau employee.

Paragraph 3. No person shall apply or affix, or cause to be applied or affixed, any trade label, stamp, or mark to any container of hog-cholera virus or antihog-cholera serum, prepared or received in a licensed establishment except in compliance with these regulations. Suitable tags or labels of a distinct design should be used for identifying all biologics while in course of preparation.

SECTION 2. *Paragraph 1.* Trade labels shall bear the true name of the product contained in the package, and this name shall be identical with that given in the license under which the product is prepared. The name shall also be so lettered and placed as to give equal prominence to each word composing it. Such labels shall also bear the name and address of the manufacturer and the license or permit number assigned by the department. The license number and permit shall be shown in either of the following forms, respectively: "U. S. Veterinary License No. ——," or "U. S. Vet. License No. ——," and "U. S. Veterinary Permit No. ——," or "U. S. Vet. Permit No. ——." These labels shall bear all other information required by the chief of bureau, and may also bear any other statement not false or misleading, and which has been approved by the bureau.

Paragraph 2. Each trade label shall bear a serial number, affixed by the manufacturer, by which the product can be identified with the records of preparation.

Paragraph 3. Each trade label shall bear a return date affixed before the product is removed from the establishments. The date shown shall be a date after which the manufacturer does not guarantee the product to be of full strength or potency.

Paragraph 4. All trade labels affixed to or used in connection with each immediate or true container shall bear a dosage table and full instructions governing the use of the product.

Paragraph 5. Trade labels affixed to the immediate or true containers of viruses and products prepared from attenuated organisms shall bear, in addition to the statements required by the preceding paragraphs of this section, the following, prominently placed and lettered: "CAUTION—BURN THIS CONTAINER AND ALL UNUSED CONTENTS."

Paragraph 6. When any virus, serum, toxin, or analogous product is prepared by a licensed establishment, or imported for a person other than the one to whom a license or permit has been issued, and the name and address of the distributor, as well as that of the manufacturer, is to appear on the trade labels of the containers thereof, a statement shall be made on the labels indicating that the virus, serum, toxin, or analogous product is distributed by such person. The name and address of this person shall not appear in any form

or manner indicating that the distributor is the producer of the product, and operating under the license as shown on the label. The terms "Distributor," "Distributors," "Distributed by," or equivalent terms may be used if prominently placed and lettered, in connection with the name and address of the distributing person, provided the same are not used so as to be either false or misleading. Reference to the distributing person shall be made by name and address only.

Paragraph 7. Copies of all trade labels before use shall be submitted to the bureau for examination and approval. These labels shall be submitted in triplicate, quadruplicate, or quintruplicate, as may be indicated. Triplicate copies of new trade labels in the form of sketches, proofs, or photographic copies should be submitted, through the inspector in charge, to the bureau for approval.

REGULATION 13.—COLLECTING SAMPLES.

SECTION 1. *Paragraph 1.* Samples of viruses, serums, toxins, and analogous products shall be collected by authorized officers, agents, or employees of the department.

Paragraph 2. Samples may be purchased in the open market, and the marks, brands, or tags upon the package or wrapper thereof shall be noted. The collector shall note the names of the vendor and agent of the vendor who made the sale, together with the date of purchase. The collector shall purchase representative samples.

Paragraph 3. All samples or parts of samples shall be sealed by the collector and marked with identifying marks.

REGULATION 14.—PRODUCTION, TESTING, ETC.

SECTION 1. Except as otherwise provided in these regulations, all viruses, serums, toxins, and analogous products shall be prepared, handled, stored, marked, treated, and tested by licensed establishments in accordance with methods prescribed by the Chief of the Bureau of Animal Industry.

REGULATION 15.—RETESTING.

SECTION 1. Viruses, serums, toxins, and analogous products, the containers of which bear United States veterinary license numbers or United States veterinary permit numbers, or any other mark required by these regulations, shall be subject to inspection at any time or place. If, as a result of such inspection, it appears that any such product, even though prepared in a licensed establishment or imported under permit issued by the Secretary, is worthless, contaminated, dangerous, or harmful, the Secretary shall give notice thereof to the manufacturer or importer and to any jobbers, dealers, or other persons known to have any of such product in their possession. Unless and until the Secretary shall otherwise direct, no person so notified shall thereafter sell, barter, or exchange in any place under the jurisdiction of the United States nor shall thereafter ship or deliver for shipment from any State, Territory, or the District of Columbia to any other State, Territory, or the District of Columbia, any of such product.

REGULATION 16.—REPORTS.

SECTION 1. *Paragraph 1.* Reports of the work of inspection carried on in every licensed establishment shall be forwarded to the bureau by the inspector in charge in such form and manner as may be specified by the chief of bureau.

Paragraph 2. Each licensed establishment shall furnish to bureau employees accurate information as to all matters needed by them for making their reports pursuant to paragraph 1 of this section, and shall submit such reports as may be required by the chief of bureau.

REGULATION 17.—ANIMALS.

SECTION 1. *Paragraph 1.* Licensed establishments which procure animals from public stockyards, abattoir pens, or similar places shall afford opportunity for all hogs, cattle, sheep, and goats admitted to the premises of such establishments to range in contact with other animals as prescribed in section 3 of this regulation.

Paragraph 2. Cattle, sheep, and goats from whatever source, except "contact calves" and those admitted by certificate as permitted by section 5 of this regulation upon admission to the premises of licensed establishments, shall be afforded opportunity to range in contact with other animals as prescribed in section 3 hereof.

SECTION 2. *Paragraph 1.* Licensed establishments shall provide suitable pens to be known as "receiving pens" through which all hogs, cattle, sheep, and goats shall pass in accordance with the provisions of this regulation before they shall be admitted to any other part of the premises.

Paragraph 2. Licensed establishments shall provide healthy calves in thrifty condition and ranging from 3 to 12 months of age for use as contact animals in receiving pens. They shall be referred to as "contact calves."

Paragraph 3. Each contact calf shall have the left ear thereof pierced with a hole not less than three-fourths inch in diameter and to the right ear of each animal shall be attached a serially numbered metal tag.

SECTION 3. *Paragraph 1.* All animals covered by section 1 of this regulation, except hogs, shall be held in receiving pens for at least 48 hours as prescribed in paragraph 2 of this section, and not less than two contact calves shall be used for each lot of 20 animals or less in the same pen.

Paragraph 2. All hogs which are admitted to the premises of licensed establishments under the provisions of section 1, paragraph 1, of this regulation, shall be held in receiving pens for at least 24 hours after admission to the premises, with the exception of pigs which are used in testing the potency and purity of anti-hog-cholera serum and the virulence of hog-cholera virus, in which case six hours will be sufficient; and during this time all these animals shall be allowed free range and contact with not less than two contact calves for each lot of 200 hogs or less in the receiving pens. Hogs immune to hog cholera may be removed from the receiving pens for hyperimmunization at any time while being held as aforesaid, provided they are returned to the receiving pens immediately after this operation.

SECTION 4. *Paragraph 1.* All surviving contact calves shall be held in the receiving pens of licensed establishments for at least one month from date of admission to receiving pens as contact calves.

Paragraph 2. The removal of contact calves from receiving pens shall be so arranged that one animal of each group of two will be replaced at the expiration of one month and the other at the expiration of two months.

Paragraph 3. Removal of contact calves from receiving pens shall be accomplished so that the animal last furnished for the purpose may be used for the maximum time permitted by the preceding paragraphs of this section. No contact calf shall be used as such more than once, but may be used for testing simultaneous virus after release as a contact animal.

Paragraph 4. Contact calves shall be carefully examined by a veterinary inspector as frequently as may be necessary to detect evidence of disease.

SECTION 5. Establishments, licensed to prepare anti-hog-cholera serum or hog-cholera virus, which procure no animals from public stockyards, abattoir pens, or similar places shall furnish a properly executed certificate in the following form covering each lot or shipment of animals offered for admission to the premises thereof, or in lieu of this said animals shall be held in contact with calves as prescribed in section 3 of this regulation. These certificates shall be signed by an authorized representative of the licensed establishment.

_____, 19

This is to certify that_____ calves / hogs which are offered for admission to the establishment of the _____ Co. are from the farm or premises of _____, in the State of _____, county of _____, township of _____, and to the best of our knowledge and belief were on said farm or premises at least 21 days prior to this date, and were not exposed to any infectious, contagious, or communicable disease, and no new stock was brought on to the said farm or premises during that time. The said animals have not been in or transported through any public stockyards, abattoir pens, or similar places, nor have they been exposed to any infectious, contagious, or communicable disease since their removal from said farm or premises.

(Signed) _____ Co.,

Per _____

SECTION 6. *Paragraph 1.* All animals presented for admission to the premises of establishments licensed to prepare anti-hog-cholera serum or hog-cholera virus shall be examined by a veterinary inspector as soon as practicable after they are received and before their removal from the receiving pens in order to determine their physical condition. No animal shall be removed from receiving pens without examination by and the permission of a veterinary inspector.

Paragraph 2. After examination, if the animals are permitted to remain upon the premises and to enter the holding pens of the establishment, they shall be given serially numbered metal tags, either prior to or at the time of inoculation or hyperimmunization.

Paragraph 3. All tags used for the identification of animals shall be attached to the ears of the animals in a manner satisfactory to the inspector in charge. The tags so attached shall be the means of assisting in identifying the animals so long as they remain on the premises.

Paragraph 4. All tags which are used to identify animals shall be furnished and attached by the licensed establishment except that, when so ordered by the chief of bureau, only tags furnished by the Bureau of Animal Industry shall be used for tagging pigs and calves used for testing anti-hog-cholera serum and hog-cholera virus, and when said tags are not in actual use they shall be held at all times in the custody of a bureau employee.

Paragraph 5. The left ear of each animal used in testing the purity and potency of viruses, serums, toxins, and analogous products shall be pierced, if of sufficient size to admit of the procedure, when the test is started, with a hole of not less than three-fourths inch in diameter, except when pigs are used in testing hog-cholera virus for purity as prescribed in paragraphs 8, 9, and 10, section 4, Regulation 18 of this order, their right ears shall be pierced as aforesaid. Animals bearing marks of the above-described character shall not be presented by licensed establishments for use in testing the purity and potency of any virus, serum, toxin, or analogous product, except that "contact calves" after release as prescribed in section 4 of this regulation and serum-treated pigs in anti-hog-cholera serum tests after release as prescribed in paragraphs 6 and 7, section 4, Regulation 19 of this order may be used once for testing hog-cholera virus for purity, provided they are healthy and their right ears then are pierced as aforesaid. Furthermore, animals with either ear removed or mutilated so as to prevent the detection of these identifying marks shall not be used in any test, if the missing or mutilated ears are needed to determine the suitability of the animals for test purposes as described herein. The piercing of the ears of animals must be accomplished in the manner prescribed in this order or in such manner as may be prescribed by the chief of bureau.

SECTION 7. Animals used in the production or testing of viruses, serums, toxins, or analogous products shall not be treated with biological products other than those which are incidental to the preparation and testing of the products prepared from or tested upon said animals, except with the approval of and in such manner as may be prescribed by the chief of bureau.

SECTION 8. *Paragraph 1.* If for any reason hyperimmune hogs are practically the only animals held upon the premises of a licensed establishment, they shall be caused to range in contact with calves in the manner prescribed in section 3 of this regulation for a period of at least 10 days prior to their being subjected to carotid or final bleeding.

Paragraph 2. All animals with which hyperimmune hogs have been held in contact as prescribed in this section shall be held on the premises of the licensed establishment and under the observation of a bureau employee for at least two weeks after the hyperimmune hogs have been destroyed.

Paragraph 3. If at any time the bureau requires that hyperimmune hogs be subjected to the tail-bleeding process only, those surviving shall be held under the supervision of a bureau employee for at least two weeks after the last tail bleeding has been collected, but this shall not operate to prevent post-mortem examinations of the animals from being made as required by these regulations.

SECTION 9. *Paragraph 1.* Hogs, cattle, sheep, or goats shall not be removed from the premises of establishments licensed to produce

anti-hog-cholera serum or hog-cholera virus without the written permission of the inspector in charge.

Paragraph 2. Permission to remove animals from the premises of establishments as described in the preceding paragraph will be given by the inspector in charge under the following conditions, provided the removal of said animals is accomplished in such a manner as will preclude the dissemination of disease.

(*a*) Animals named in paragraph 1 of this section that are not in a healthy condition as determined by a veterinary inspector, except when affected with a communicable disease other than hog cholera and tuberculosis, may be removed from establishments for immediate slaughter in a federally inspected abattoir if they are transported thereto by truck, wagon, or similar means and not by rail, provided they are properly marked for identification and the inspector in charge of meat inspection is given due notice thereof in advance.

If a federally inspected abattoir is not accessible as aforesaid, the slaughter of said animals may be conducted in any convenient unofficial abattoir provided the licensed establishment signifies its willingness in writing to dispose of the carcasses under the provisions of the meat-inspection regulations and as directed by a veterinary inspector after a post-mortem examination has been conducted by him.

(*b*) Hogs that are in a healthy condition as determined by a veterinary inspector may be removed from establishments provided they are or have been treated or vaccinated and disinfected as prescribed in paragraphs 3 and 4 of this section. Such hogs need not be vaccinated or disinfected by the establishment when removed for immediate slaughter in a federally inspected abattoir or to a public stockyards from which no hogs are permitted to be removed for purposes other than immediate slaughter without vaccination and disinfection under bureau supervision. When hogs are removed to abattoirs or public stockyards without vaccination and disinfection as aforesaid, the licensed establishment shall furnish the bureau with a certificate from the consignee of the animals at the abattoir or public stockyards showing their slaughter therein or receipt thereby, respectively. If the animals are not disinfected, they shall not be transported by rail or driven over public highways which are not traversed by animals from stockyards or similar places.

(*c*) Calves that are in a healthy condition as determined by a veterinary inspector may be removed from establishments after disinfection as described in subdivision (*a*), paragraph 4 of this section, except that when removed to an abattoir without passing through stockyards, or over public highways which are not traversed by animals from public stockyards or similar places, the animals need not be so disinfected provided the licensed establishment furnishes the bureau with a certificate from the consignee of the animals at the abattoir showing their slaughter therein.

(*d*) Pigs which survive inoculation and exposure to hog cholera for the production of hog-cholera virus, surviving pigs which have been used for testing hog-cholera virus, and surviving control pigs in tests of anti-hog-cholera serum may be removed from establishments not earlier than 15 days subsequent to the time of inoculation and exposure as aforesaid, provided they are healthy, as determined

by a veterinary inspector, and are first given the serum-alone treatment as described in subdivision (*a*), paragraph 3, and are disinfected as set forth in subdivision (*b*), paragraph 4 of this section, except that when removed for immediate slaughter or to public stockyards as defined in subdivision (*b*) of this paragraph, said animals need not be so treated or disinfected.

(*e*) Hyperimmune hogs, or those treated in a similar manner, and pigs which have been used for testing anti-hog-cholera serum may be removed from establishments not earlier than 21 days subsequent to the time of hyperimmunization or inoculation, provided they are healthy, as determined by a veterinary inspector, and are disinfected as prescribed in subdivision (*b*), of paragraph 4 of this section, except that when removed for immediate slaughter or to public stockyards as set forth in subdivision (*b*) of this paragraph, said animals need not be so disinfected.

Paragraph 3. All hogs which require treatment or vaccination as defined in the preceding paragraph of this section shall be treated as follows:

(*a*) *Serum-alone method.* The serum used shall have been prepared and released for marketing at an establishment holding a license from the Secretary of Agriculture and the dose employed shall conform to that required in Regulation 19 of this order.

(*b*) *Simultaneous-inoculation method.*—The serum and virus used shall have been prepared at an establishment holding a license from the Secretary of Agriculture and the doses shall be not less than those required in Regulations 18 and 19 of this order. After receiving this treatment they shall be held under the supervision of a bureau employee for a period of at least 21 days, except when treated with virus and serum released for marketing.

Paragraph 4. All animals which require disinfection as defined in paragraph 2 of this section shall be treated as follows:

(*a*) The feet, legs, and soiled portions of the body of calves to be removed from establishments shall be cleaned and disinfected with a 2 per cent aqueous solution of cresol compound, U. S. P., or permitted substitute therefor, and these animals shall then be held in noninfectious pens on the premises of the establishment until they are dry before being loaded for transportation.

(*b*) Hogs shall be disinfected in a 2 per cent aqueous solution of cresol compound, U. S. P., or a permitted substitute therefor, and be held in noninfectious pens on the premises for at least three hours before being loaded for transportation, except that hogs transported in trucks, wagons, or by similar means may be removed as soon after disinfection as they are observed by a veterinary inspector to be thoroughly dry, if said animals are not made wet before their removal from the premises.

SECTION 10. Except as otherwise provided in these regulations, all animals used by licensed establishments in the preparation or testing of veterinary biologics shall meet such requirements as may be prescribed by the chief of bureau and deemed by him necessary to prevent the preparation and sale of any worthless, contaminated, dangerous, or harmful viruses, serums, toxins, or analogous products.

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SECTION 11. Each licensed establishment shall adopt such measures as the chief of bureau shall from time to time prescribe for carrying out the provisions of this regulation.

REGULATION 18.—HOG-CHOLERA VIRUS

SECTION 1. *Paragraph 1.* All operations incident to the production of hog-cholera virus shall be conducted under the supervision of a bureau employee. Each licensed establishment shall notify the inspector in charge or his assistant a reasonable time in advance whenever any operations are to be conducted.

Paragraph 2. Pigs which are used in the production of hog-cholera virus shall be healthy, and the temperature of each animal shall be accurately taken and permanently recorded by the establishment immediately before inoculation when in the opinion of the inspector in charge this is necessary to determine the health of the animals. Each animal shall be subjected to a careful examination by a veterinary inspector immediately prior to inoculation.

Paragraph 3. Temperatures of all pigs used to produce hog-cholera virus shall be correctly taken and recorded by licensed establishments each day subsequent to the fourth day after inoculation and at such other times as the inspector in charge may deem necessary. The temperature of each pig invariably shall be taken and recorded on each day the animal is slow or visibly sick.

Paragraph 4. Pigs from which virus for the inoculation of other pigs in the production of virus is derived shall weigh not more than 100 pounds each. Hog-cholera virus of licensed establishments shall not be used for inoculating pigs for the production of virus later than 15 days after the date of its collection, but such virus which is not more than 60 days old and which has been held continuously by licensed establishments at a temperature of not more than 55° F. (12.8° C.) may be made suitable for said inoculation purposes by passing it through pigs of the same weights and in the same manner as prescribed in paragraph 3, section 1, Regulation 21 of these regulations. The virus derived from these pigs may be used for hyperimmunization if the animals react as prescribed in the following paragraph of this section.

Paragraph 5. Pigs from which blood is to be collected for the production of hog-cholera virus shall be killed only after permission has been given by a veterinary inspector who has observed them to manifest well-marked and increasingly grave symptoms of hog cholera only, attended with progressively abnormal temperatures common to the acute type of this disease. These pigs shall be free from other communicable diseases, except as provided in paragraph 9 of this section.

Paragraph 6. All pigs from which hog-cholera virus is derived shall be subjected to a post-mortem examination by a veterinary inspector, except that trained lay inspectors may conduct these examinations on hyperimmunizing virus pigs subject to review by a veterinary inspector, who should make all decisions on questionable matters.

Paragraph 7. Hog-cholera virus derived from pigs which become visibly sick within three days after the time they are admitted to the

premises of licensed establishments shall be destroyed as provided in section 11, Regulation 8, under the supervision of a bureau employee.

Paragraph 8. Hog-cholera virus derived from pigs which upon post-mortem examination do not show lesions sufficient for a veterinary inspector to make a positive diagnosis of hog cholera, when considered with the ante-mortem behavior of the animal, or which are found to be so affected with any infectious, contagious, or communicable disease, or in such condition as to render the virus contaminated, shall be destroyed as provided in section 11, Regulation 8, under the supervision of a bureau employee. Virus passed by bureau employees may be destroyed as aforesaid at the discretion of the establishment.

Paragraph 9. Hog-cholera virus derived from pigs which are found to be affected with tuberculosis shall be destroyed as provided in section 11, Regulation 8, under the supervision of a bureau employee, unless the lesions are slight or are localized, and are calcified or encapsulated. Hog-cholera virus derived from pigs affected as described shall not be marketed.

Paragraph 10. All records shall indicate clearly the particular animal, or group of animals, from which each batch of hog-cholera virus is derived. The amount collected and the total amount after phenolization should be separately recorded.

Paragraph 11. Hog-cholera virus shall not be removed from the premises of a licensed establishment unless the virus has been prepared in accordance with the provisions of these regulations.

Paragraph 12. No immediate or true container of hog-cholera virus shall be filled in whole or in part, and no trade label shall be affixed to such container except under the supervision of a bureau employee.

Paragraph 13. The following special facilities, and such others as may be required by the chief of bureau, shall be provided by each establishment licensed to prepare hog-cholera virus:

(*a*) Separate operating rooms.

(*b*) A separate room in which the animals shall be washed, cleaned, and otherwise prepared before being taken into the operating room.

(*c*) A separate room for conducting autopsies.

(*d*) A separate room for the preparation and mixing of virus.

(*e*) A separate room for washing and sterilizing equipment.

(*f*) Clean cloths which shall be kept damp when in use, to be used for covering pigs during all operations incident to the collection of hog-cholera virus.

(*g*) All outside doors, openings, and windows shall be equipped with dust screens.

Paragraph 14. All persons immediately before entering the operating or laboratory rooms of an establishment licensed to prepare hog-cholera virus when these rooms are in use, shall change their outer clothing or cover it by the use of clean gowns or other satisfactory garments.

Section 2. *Paragraph 1.* For use in the production of hyperimmunizing virus, licensed establishments shall inoculate young pigs weighing not more than 145 pounds each with at least 2 cubic centimeters of a virulent strain of hog-cholera virus, except that when sickness from pen infection is manifested by the animals after the fourth day subsequent to admission to the premises, they need not be so inoculated.

Paragraph 2. Hyperimmunizing virus shall be collected only from pigs which are observed by a veterinary inspector to be visibly sick with hog cholera and which manifest well-marked and increasingly grave symptoms thereof attended with progressively abnormal temperatures common to the acute type of this disease.

SECTION 3. *Paragraph 1.* For use in the production of simultaneous virus, licensed establishments shall inoculate young pigs, weighing not less than 40 pounds nor more than 100 pounds each, with at least 2 cubic centimeters of a virulent strain of hog-cholera virus.

Paragraph 2. Simultaneous virus shall not be collected from pigs which become visibly sick on or before the third day, or subsequent to the sixth day after the time of inoculation. The physical condition of pigs from which simultaneous virus is collected shall be recorded daily on and after the third day subsequent to inoculation.

Paragraph 3. Simultaneous virus and hog-cholera virus intended for the inoculation of pigs for any purpose shall be collected only from pigs which are observed by a veterinary inspector to be visibly sick with hog cholera within six days after the time of inoculation and which manifest well-marked and increasingly grave symptoms of hog cholera attended with progressively abnormal temperatures common to the acute type of this disease.

Paragraph 4. Simultaneous virus and virus intended for inoculation purposes shall be defibrinated promptly after collection, and immediately thereafter chilled and maintained at a temperature not to exceed 55° F. (12.8° C.).

Paragraph 5. Should it become necessary under the provisions of these regulations to require the heating of simultaneous virus to prevent the possibility of disseminating infections, this shall be accomplished in such manner as may be prescribed by the chief of bureau.

Paragraph 6. Simultaneous virus which has been heated, as provided in the preceding paragraph, shall not be handled thereafter in a manner which will expose the product to contamination.

Paragraph 7. Simultaneous virus shall be tested for virulence by inoculating in the axillary space or intramuscularly with 2 cubic centimeters of the virus to be tested, each of four or more pigs which are susceptible to hog cholera. Should not less than 75 per cent of the pigs thus inoculated become affected with hog cholera as required for pigs inoculated to furnish simultaneous virus, the test will be declared "Satisfactory for virulence." Should this test be found unsatisfactory a retest may be made.

Paragraph 8. Pigs selected for testing the virulence of simultaneous virus shall be inoculated within eight hours after their admission to the premises. The quarters where these pigs are held during the test shall be isolated as completely as feasible from quarters occupied by other pigs exposed to or sick with hog cholera. All reasonable precautions shall be taken to prevent infection of these pigs from sources other than by inoculation. Such precautions shall include a thorough cleaning and disinfection of the pens in which the pigs are held on the premises, and a disinfection of these animals after they are placed in holding pens. The disinfection of these pens and the test pigs shall be accomplished with a 2 per cent aqueous solution of cresol compound, U. S. P., or by such methods as shall be approved by the chief of bureau.

SECTION 4. *Paragraph 1.* Simultaneous virus shall be collected in batches of not to exceed 20,000 cubic centimeters each and each batch shall be mixed thoroughly in a single container before phenolization, and by constant agitation during the bottling process.

Paragraph 2. After mixing, but before phenolization, a representative sample of each batch, consisting of at least 15 cubic centimeters of the mixture, shall be taken by a bureau employee. This sample shall be known as the "virus-test sample."

Paragraph 3. Simultaneous virus which has been mixed as provided in this section, after withdrawal of the "virus-test sample," shall have added to it a sufficient quantity of a 5 per cent solution of phenol so that the virus will contain one-half of 1 per cent phenol by volume. This phenolization must be accomplished with accuracy and in a manner which will prevent undesirable changes in the product. After thorough mixing in a single container, a representative sample, consisting of at least 100 cubic centimeters, collected in three containers, shall be taken by a bureau employee. This sample shall be known as the "virus-stock sample."

Paragraph 4. Simultaneous virus which has been mixed and phenolized, as provided in this section, together with the virus-stock sample and the unused residue of the virus-test sample, shall be placed under bureau lock and held as provided under subdivision (*b*), section 1, of Regulation 7 until such time as required test has shown the batch of virus to be virulent as prescribed in paragraph 7, section 3, of this regulation and free from contamination.

Paragraph 5. At least one container of the virus-stock sample shall be held unopened under bureau lock, in the manner provided in Regulation 7, for at least three months after the expiration of the latest return date shown upon the trade labels affixed to the immediate or true containers of the product corresponding to the virus-stock sample. The virus-test sample described in paragraph 2 of this section shall be used to determine the freedom from contamination of each batch of simultaneous virus.

Paragraph 6. Two healthy calves, with mouths free from abrasions, and not less than 3 nor more than 12 months old, or three healthy pigs immunized by the simultaneous treatment against hog cholera for at least 21 days, shall be furnished by the establishment for inoculation with the virus-test sample.

Paragraph 7. All animals used for the testing of simultaneous virus shall be inoculated only under the supervision of a veterinary inspector, and shall be marked as provided in paragraphs 2, 3, 4, and 5, section 6, of Regulation 17.

Paragraph 8. Each of the animals selected for testing the purity of simultaneous virus shall be inoculated by injecting 5 cubic centimeters of the virus-test sample into either the auricular or the jugular vein within 24 hours after the virus is collected.

Paragraph 9. Animals inoculated for the purpose of determining the purity of simultaneous virus as provided in the preceding paragraph shall be held under the observation of a veterinary inspector for a period of at least seven days. Should foot-and-mouth disease appear in the United States the said animals shall be held under the observation of a veterinary inspector for 10 days or longer, at the discretion of the inspector in charge.

Paragraph 10. If the animals which are treated with hog-cholera virus as prescribed in the preceding paragraph of this section do not manifest symptoms of any infectious, contagious, or communicable disease except as hereinafter provided, the test will be declared "Satisfactory for purity," and if the product has been found "satisfactory for virulence," as defined in paragraph 7, section 3, of this regulation, it will be released for marketing. Should any of the animals in the test succumb or should more than one develop hog cholera, another test should be made as in the first instance, except that not less than 15 cubic centimeters of the virus should be used for the inoculation of each animal if the virus contains preservative.

Paragraph 11. Simultaneous virus found to be worthless or contaminated shall be destroyed as provided in section 11, Regulation 8, under the supervision of a bureau employee.

SECTION 5. *Paragraph 1.* Each immediate or true container of hog-cholera virus which has been tested and not found to be worthless or contaminated may bear over the opening of its neck a paper cap attached by the establishment and on which may appear the words, "U. S. Released." Whenever caps bearing the aforesaid words are applied, they shall be serially numbered and bear the license legend of the establishment properly separated from the words and number aforesaid. It shall be affixed only after approval thereof by the bureau and under the supervision of a bureau employee. When these caps are not in use they shall be held under bureau lock. Strong, flexible bands perforated as hereinafter described shall be used to hold the aforesaid caps securely over the openings of the containers of the product. All perforations of said bands shall consist of the number of the license under which the product is produced, a number assigned to the batch to which the perforated band is affixed, and the last figure in the number used for indicating the calendar year. (Illustration: 190.18.2=License No. 190; batch 18; year 1922.) The perforating machine when not in use for perforating bands as aforesaid shall be held under bureau lock.

Paragraph 2. The trade label on each immediate or true container of simultaneous virus shall bear the date of manufacture, which date shall be the day on which the virus is collected.

Paragraph 3. The return date placed upon the label of each immediate or true container of simultaneous virus shall be a date within 60 days after the date of manufacture.

Paragraph 4. Trade labels affixed to or used in connection with the immediate or true containers of hog-cholera virus shall show plainly the amount of the contents of said containers.

Paragraph 5. Trade labels affixed to or used in connection with each immediate or true container of simultaneous virus shall bear a dosage table in which the doses recommended are not less than those appearing in the following table:

Weight.	Minimum dose.
Pigs weighing 45 pounds or less	1 c. c.
Pigs weighing more than 45 pounds	2 c. c.

Paragraph 6. No hog-cholera virus shall be released for marketing unless and until all information required by these regulations has been affixed to the containers thereof under the supervision of a bureau employee.

REGULATION 19.—ANTI-HOG-CHOLERA SERUM.

SECTION 1. *Paragraph 1.* All operations incident to the production of anti-hog-cholera serum shall be conducted under the supervision of a bureau employee. Each licensed establishment shall notify the inspector in charge, or an assistant, a reasonable time in advance whenever any operations are to be conducted.

Paragraph 2. Principle: Pigs that develop hog cholera of a well-marked and progressive type attended with progressively abnormal temperatures produce hog-cholera virus of great virulence, and when hogs properly immunized against hog cholera for a sufficient length of time are injected intravenously with massive quantities of such virus their blood serum is possessed of superior protective properties against hog cholera. Therefore, these principal facts should form the basis of all methods of producing anti-hog-cholera serum and hog-cholera virus as well as of all regulations governing their production.

SECTION 2. *Paragraph 1.* Anti-hog-cholera serum shall be derived only from hyperimmune hogs which have been immune to hog cholera for at least 90 days prior to hyperimmunization.

Paragraph 2. Anti-hog-cholera serum shall be derived only from hyperimmune hogs which have been subjected to not more than 4 successive bleedings after each hyperimmunization. The first bleeding shall take place not earlier than 10 days after hyperimmunization. subsequent bleedings shall not take place more frequently than once in 7 days, and the last bleeding shall be made on a date not later than 38 days after hyperimmunization.

Paragraph 3. Hogs which are used to produce anti-hog-cholera serum shall be healthy at the time of hyperimmunization, this fact to be determined by a careful examination made by a veterinary inspector prior to hyperimmunization. The temperature and weight of each animal shall be accurately obtained and recorded by the establishment before hyperimmunization.

Paragraph 4. All hogs which are used to produce anti-hog-cholera serum at each hyperimmunization shall receive a single intravenous injection of at least 5 cubic centimeters of hog-cholera virus for each pound of the animal's weight.

Paragraph 5. The temperatures of all hogs used to produce anti-hog-cholera serum shall be accurately taken with reliable thermometers and recorded by licensed establishments either on the afternoon before or on the day of bleeding and at such other times as the inspector in charge may deem necessary. All temperatures shall be taken under normal conditions on groups of hogs to be bled on the same date and without undue delay. Clean, light quarters equipped with a temperature chute and all other needed facilities for expediting the work and satisfactory inspection shall be provided.

Paragraph 6. All hogs which are used to produce anti-hog-cholera serum shall be subjected to a careful examination by a veterinary inspector immediately prior to each bleeding. Only those hogs shall be bled for serum which are found to have a temperature of less than 104° F. and are free from infectious, contagious, or communicable diseases or other abnormal conditions.

Paragraph 7. Anti-hog-cholera serum derived from hogs which after hyperimmunization manifest symptoms indicative of an affec-

tion of a constitutional character other than those usually observed immediately following hyperimmunization shall not be mixed with other serum unless after consideration of the prevailing conditions this action is permitted by the chief of bureau. Such serum, if collected only from hogs as prescribed in the preceding paragraph, may be mixed alone and tested as prescribed in this regulation, and if, as a result of this test, the product is found satisfactory, it may be marketed. Otherwise the serum will be destroyed, as provided in section 11, Regulation 8, under the supervision of a bureau employee.

Paragraph 3. All hogs from which anti-hog-cholera serum is derived shall be subjected to a post-mortem examination by a bureau employee. Should conditions warrant the procedure, trained lay inspectors may be authorized by the inspector in charge to make preliminary examinations as aforesaid, but the carcasses of these hogs should be retained for final examination by a veterinary inspector, and the viscera of all that bear evidence of any abnormality must also be subjected to examination in like manner. If, as a result of such examination, it is found that any hog is so affected with any infectious, contagious, or communicable disease or is in such condition as to render the serum worthless, contaminated, dangerous, or harmful, the serum collected from such hogs shall be destroyed by the establishment, as provided in section 11, Regulation 8, under the supervision of a bureau employee, except that serum derived from tuberculous hogs need not be so destroyed when the lesions are slight or are localized and are calcified or encapsulated, or when the product from tuberculous hogs is clarified and heated or tested by methods approved by the chief of bureau, or when refined and heated or tested as aforesaid.

Paragraph 9. Anti-hog-cholera serum derived from each hyperimmune hog shall be kept separate and apart from other serum except when heated as prescribed in paragraph 11 of this section, until it has been determined by post-mortem examination that the hog from which the serum is derived is not so affected with any infectious, contagious, or communicable disease or is in such condition as to render the serum worthless, contaminated, dangerous, or harmful.

Paragraph 10. When anti-hog-cholera serum is heated as described in the following paragraph the serum derived from each hyperimmune hog may be mixed with serum from other hyperimmune hogs immediately after collection, provided the final batch or mixture is prepared and handled as prescribed in the following paragraph of this section.

Paragraph 11. Heating of anti-hog-cholera serum shall be conducted under the supervision of a bureau employee and in a manner in which the product and the entire container thereof will be subjected to a temperature ranging from 59° to 60° C. for 30 minutes.

Paragraph 12. Anti-hog-cholera serum which has been heated as provided in the preceding paragraph shall not be handled thereafter in a manner which will expose the product to contamination. Final mixtures or batches of anti-hog-cholera serum shall contain relative proportions of the several bleedings. Single bleedings from each hog shall not be divided or become a part of two or more batches unless the serum is subjected to heat as described in paragraph 11 of this section.

Paragraph 13. Whenever practicable, all the blood from a given number of hyperimmune hogs should be placed in the same batch, but, in order that the batch may closely approximate 100,000 cubic centimeters, as many individual bleedings of any one hog's blood as required for this purpose may be used and the remainder, if any, of such individual hog's blood should be placed in another single batch. In selecting a bleeding for this purpose the one which will cause the batch most closely to approximate 100,000 cubic centimeters should be used.

Paragraph 14. Anti-hog-cholera serum which is to constitute a batch or portion thereof may be strained into a single container, after which the amount should be accurately determined.

Paragraph 15. Ordinary defibrinated blood anti-hog-cholera serum shall have added thereto a sufficient quantity of a 5 per cent solution of phenol to make the completed serum contain one-half of 1 per cent phenol by volume. Clear anti-hog-cholera serum shall be preserved likewise, unless otherwise permitted by the chief of bureau.

Paragraph 16. Phenolization of anti-hog-cholera serum must be accomplished with accuracy, and in a manner which will prevent the occurrence of undesirable changes in the product.

Paragraph 17. All records shall indicate clearly the particular hog or group of hogs from which each batch of serum or portion thereof is derived. The amount prepared for phenolization and the total amount after phenolization shall be separately recorded.

SECTION 3. *Paragraph 1.* Anti-hog-cholera serum prior to testing shall be collected in batches of not more than approximately 100,000 cubic centimeters each, which shall be thoroughly mixed in a single container, by constant agitation during the bottling process. After mixing and phenolizing, a representative sample consisting of at least 375 cubic centimeters collected in three containers of not less than 125 centimeters, each to be known as the "serum-test sample," shall be taken and marked with identifying marks by a bureau employee. The serum, together with the test sample, shall be placed under bureau lock, as provided under subdivision (*b*) section 1, Regulation 7, and so held until such time as the tests required by these regulations have been completed, and have indicated that the serum is not worthless, contaminated, dangerous, or harmful.

Paragraph 2. If the serum is released, one of the three containers of the test sample thereof shall be held under bureau lock for at least six months after the latest return date shown on the trade labels affixed to the immediate or true containers of the serum of which the test sample is a part.

Paragraph 3. Test samples of anti-hog-cholera serum on which the return date has expired six months previously may be labeled and marketed in the regular manner, provided it is feasible, within two years after the first serum composing the batch is collected. When not feasible, and it is desired to market the serum, the samples should be mixed and assigned a serial number. This mixture may be tested alone or it may be mixed with other untested serum and tested as prescribed in sections 4 and 5 of this regulation provided the latter does not represent more than 50 per cent of the serum contained in the final mixture. The return date to be affixed

to the containers of mixtures of test samples should not exceed one year from the date of conclusion of a satisfactory test for potency.

SECTION 4. *Paragraph 1.* All anti-hog-cholera serum shall be tested for purity and potency by licensed establishments as prescribed by these regulations.

Paragraph 2. For use in testing each batch of 100,000 cubic centimeters of anti-hog-cholera serum or less, eight healthy pigs, susceptible to hog cholera and weighing not less than 40 pounds and not more than 90 pounds each, shall be furnished by the establishment, except as provided in sections 7, 8, and 9 of this regulation.

Paragraph 3. Each of the eight pigs furnished for the test shall be injected with 2 cubic centimeters of hog-cholera virus; of these pigs, five shall receive 20 cubic centimeters of the serum which is to be tested. Three of the pigs shall receive no serum and shall serve as controls. The virus and serum injections shall be made simultaneously, the virus being injected into the left axillary space, and the serum into the right. The same virus shall be used for the inoculation of all pigs in the test and shall be selected and administered by a veterinary inspector.

Paragraph 4. A veterinary inspector shall indicate the pigs which shall receive serum with virus and those which shall receive the virus only in each serum test.

Paragraph 5. All surviving pigs used for testing a batch of serum shall be subjected to the same conditions throughout the test period and shall be held in a single pen or inclosure throughout this period except when it is evident that a test of serum will be declared "No test" or "Unsatisfactory for potency," the test pigs, with the permission of a bureau employee, may be removed from the original test pen and placed with other pigs of the same class in a common pen for the purpose of releasing test pen space for other tests.

Paragraph 6. The period for holding surviving pigs under the observation of a bureau employee, while being used for testing the potency and purity of anti-hog-cholera serum as described in this regulation, shall be not less than 21 days immediately following their inoculation for this purpose, and as much longer as the inspector in charge deems necessary to render proper judgment of the results of the test. If not more than one serum-treated pig succumbs within 15 days after inoculation, however, or if it becomes necessary to retest a batch of serum for purity only, 15 days immediately following the inoculation of the pigs will constitute the period for testing the purity of the product.

Paragraph 7. Pigs in serum tests shall be held under the observation of a veterinary inspector and shall not be removed from the test unless and until released by such an inspector, who will permit their removal after they have served their purpose in the test as prescribed in this regulation.

Paragraph 8. The temperature of each pig used in a test of anti-hog-cholera serum shall be taken and recorded shortly before each test is started.

Paragraph 9. Temperatures of control pigs and "slow" or sick serum-treated pigs in serum tests, excepting known "Unsatisfactory tests" and "No tests," shall be taken daily throughout the test period, but not on Sundays and holidays when these days are of no particular consequence to the proper disposition of the test, and an accurate

report of these temperatures shall be rendered by the establishment to the inspector in charge as he may direct.

Paragraph 10. When serum-treated pigs do not manifest "slowness" or symptoms of sickness their temperatures need not be taken except when required by the inspector in charge or his assistant to determine more accurately the true physical condition of the animals under observation.

Paragraph 11. Simultaneous virus or its equivalent of high virulence and in sufficient quantities to meet the needs shall be furnished by licensed establishments for use as the inspector in charge may deem advisable for inoculating pigs in serum tests. Virus furnished by licensed establishments shall not be used in a serum test if it has been collected for more than 30 days previous to the inauguration of the test, but tests of virus required by these regulations shall not operate to prevent the use of the product in serum tests at any time within 30 days after its collection.

Paragraph 12. Hog-cholera virus furnished by the Bureau of Animal Industry may be used in inoculating pigs in tests whenever the inspector in charge deems this procedure advisable, and whenever conditions in previous tests of any batch of serum have indicated some deficiency in either the virus or serum used.

Section 5. *Paragraph 1.* The following principle and rules are declared for a guide in judging the results of serum tests:

Principle: It is practically impossible in many cases to differentiate accurately between hog cholera, pneumonia, and other conditions affecting hogs without the aid of an autopsy as well as applied laboratory technic and certain experiments which may be necessary to determine the causative agent responsible for the condition. Therefore, when healthy pigs are selected for testing anti-hog-cholera serum any abnormal condition which may arise in the pigs subsequent to their inoculation should be regarded as due either to the virus used or, in the case of the serum-treated pigs, to the fact that the serum does not protect, unless the condition is definitely known or can be shown to be due to some other cause.

Paragraph 2. The following rules shall be observed in disposing of anti-hog-cholera serum which has been subjected to the tests prescribed by these regulations:

Rule A. The purpose of control pigs in serum tests will be to furnish information as to the virulence of the virus used for inoculating the animals and to indicate whether the pigs furnished are properly susceptible to hog cholera. As an aid for determining the fulfillment of this purpose the following conditions shall obtain:

1. At least two of the control pigs shall become visibly sick of hog cholera subsequent to the third day of the test period and within seven days after the test is inaugurated.

2. At least two of the control pigs which become sick as described in the preceding paragraph of this rule shall manifest well-marked and increasingly grave symptoms of hog cholera attended with progressively abnormal temperatures common to the acute type of this disease.

3. At least two of the control pigs, which become sick as described in the preceding paragraphs of this rule, shall show lesions upon post-mortem examination sufficient for a veterinary inspector to

make a positive diagnosis of hog cholera, when considered with the ante-mortem behavior of these animals.

Rule B. A serum test will be declared "Satisfactory for potency" when at least two of the control pigs react as described in rule A of this regulation and any one of the following conditions obtains:

1. When all the serum-treated pigs remain well throughout the test period.

2. When not more than one of the serum-treated pigs becomes visibly sick after the time of inoculation and fully recovers before the test animals are released by a veterinary inspector as provided in this regulation. Such a sick pig, however, will not be regarded as having fully recovered until it has been in an apparently normal condition for at least three days.

Rule C. A serum test will be declared "Unsatisfactory for potency" when at least two of the control pigs react as described in rule A of this regulation and any one of the following conditions obtains:

1. When one of the serum-treated pigs becomes visibly sick subsequent to the third day after the time of inoculation and is found not to have fully recovered before the test animals are released by a veterinary inspector as provided in this regulation.

2. When two or more of the serum-treated pigs become visibly sick subsequent to the third day after the time of inoculation.

Rule D. A serum test will be declared "No test for potency" when any one of the following conditions obtains, but such action will not operate to prevent a retest under the provisions of these regulations.

1. When one of the serum-treated pigs becomes visibly sick on or before the third day after the time of inoculation and fails to recover within the test period.

2. When two or more of the serum-treated pigs or two or all of the control pigs become visibly sick on or before the third day after the time of inoculation.

3. When two or all of the control pigs do not manifest symptoms of hog cholera as described in rule A of this regulation.

4. When two or all of the control pigs do not show lesions of hog cholera upon post-mortem examination as described in rule A of this regulation.

5. When two or all of the control pigs manifest symptoms of hog cholera within seven days as described in rule A of this regulation but do not become sick to the degree described in said rule.

6. When the serum-treated pigs develop during the test period symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is not caused by the serum used.

7. When a condition obtains in any of the test pigs which is not otherwise covered in this section.

Rule E. A serum test will be declared "Satisfactory for purity" when the following condition obtains:

1. When not more than one of the serum-treated pigs in the test develops an abscess at the site of the serum injection and no symptoms of any infectious, contagious, or communicable disease other than hog cholera are manifested by any of the animals in the test.

Rule F. A serum test will be declared "Unsatisfactory for purity" when either of the following conditions obtains:

1. When abscesses which are not definitely known to be due to causes other than the serum used develop at the sites of the serum injections in more than one of the serum-treated pigs.

2. When during the test period any of the serum-treated test pigs develop symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is due to the serum used.

Rule G. A serum test will be declared "No test for purity" when any one of the following conditions obtains, but such action will not operate to prevent a retest under the provisions of these regulations.

1. When two or more of the serum-treated pigs succumb within 15 days after the time of inoculation.

2. When the serum-treated pigs develop during the test period symptoms of any infectious, contagious, or communicable disease (other than hog cholera) which is not caused by the serum used.

3. When a condition obtains in any of the test pigs which is not otherwise covered in this section.

SECTION 6. *Paragraph 1.* Anti-hog-cholera serum may be released for marketing as hereinafter prescribed when the tests required by this regulation are found to be satisfactory as defined in rules B and E hereof, provided the product is recommended for use in doses not less than those appearing in the following table. This table shall be a part of trade labels, wrappers, and the like, affixed to or used in connection with each immediate or true container of the product.

Weight.	Minimum dose.
Sucking pigs	20 c. c.
Pigs 20 to 40 pounds	30 c. c.
Pigs 40 to 90 pounds	35 c. c.
Pigs 90 to 120 pounds	45 c. c.
Hogs 120 to 150 pounds	55 c. c.
Hogs 150 to 180 pounds	65 c. c.
Hogs 180 pounds and over	75 c. c.

Paragraph 2. Anti-hog-cholera serum the test of which has proved it to be "Unsatisfactory for potency," as defined in rule C of this regulation, may be tested again as described in sections 4 and 5 of this regulation. Should the second test prove to be "Satisfactory for potency," as defined in rule B, the serum may be released for marketing under the condition set forth in paragraph 1 of this section. If the test is again found "Unsatisfactory for potency," as defined in rule C, the serum shall not be marketed unless and until it is either refined, concentrated, and tested in a manner approved by the chief of bureau, or mixed with other serum and tested as provided in section 7 of this regulation.

SECTION 7. *Paragraph 1.* Anti-hog-cholera serum found twice "Unsatisfactory for potency" as described in rule C of this regulation but which is "Satisfactory for purity" as described in rule E hereof may be mixed with other anti-hog-cholera serum with the view of increasing its potency and the final mixture shall consist of not less than 50 per cent nor more than 60 per cent of the serum of doubtful potency in the case of ordinary defibrinated-blood serum. Clear serum found "Unsatisfactory for potency" as aforesaid should not be mixed with other serum except as may be permitted by the chief of bureau.

Paragraph 2. Anti-hog-cholera serum which has been mixed as provided in the preceding paragraph shall be tested as outlined in sections 4 and 5 of this regulation, with the exception that 11 pigs in lieu of 8 shall be used and 8 of these shall receive serum.

Paragraph 3. A second test, conducted in the same manner as before, may be made of serum mixed as provided in paragraph 1 of this section, should the results of the test of the mixture be declared "Unsatisfactory for potency." Should the second test also prove to be "Unsatisfactory for potency" the product shall not be marketed unless and until it is refined, concentrated, and tested in a manner approved by the chief of bureau.

SECTION 8. *Paragraph 1.* Should abscesses develop at the sites of the serum inoculations in any of the pigs used for testing serum as provided in this regulation, the following rules shall apply:

(*a*) Judgment of the results of tests made on pigs to determine the potency of anti-hog-cholera serum will be rendered irrespective of those conditions found which are regarded as an index to the purity of the product.

(*b*) Should the results of a test of anti-hog-cholera serum be declared "Satisfactory for purity," and it is found necessary to subject the batch of serum to a retest to determine its potency, judgment concerning the purity of the product shall be based upon the first test unless evidence is found subsequent to such test which indicates that the serum is in fact contaminated.

(*c*) Anti-hog-cholera serum which has been found "Unsatisfactory for purity" as defined in subdivision 1, rule F, of this regulation, may be tested again for purity upon eight pigs, provided each pig receives a single injection, in the axillary space, of at least 20 cubic centimeters of the product to be tested. Immune pigs may be used for this test, provided the product has already been found "Satisfactory for potency."

SECTION 9. *Paragraph 1.* Anti-hog-cholera serum which has been found twice "Unsatisfactory for purity" as defined in subdivision 1, rule F, of this regulation, but which is "Satisfactory for potency," as prescribed in rule B hereof, may be tested again with the view of ascertaining whether it is in fact contaminated with pus-producing organisms, by treating 50 hogs on the premises of the manufacturing establishment. The serum shall be administered under the supervision of a bureau employee, and each hog treated shall receive a single injection, in the axillary space, of not less than 25 cubic centimeters of the product to be tested.

Paragraph 2. Animals used for testing serum as prescribed in paragraph 1 of this section shall be held under the supervision of a bureau employee for at least 15 days, and each animal carefully examined at the sites of the inoculations to determine whether the product has caused abscess formation. Serum tested as prescribed in this section will be disposed of as approved by the chief of bureau.

SECTION 10. *Paragraph 1.* Blood derived from hyperimmune hogs and ordinary defibrinated blood anti-hog-cholera serum may be clarified or refined and concentrated by licensed establishments, provided methods used to accomplish this are approved by the chief of bureau.

Paragraph 2. When hyperimmune blood and ordinary defibrinated blood anti-hog-cholera serum that has not been found "Unsatisfactory for potency" are to be clarified or refined, the following requirements shall be observed:

(*a*) When unconcentrated clear serum is prepared, the completed product shall contain not less than 65 per cent of true serum and shall represent not more than 98 per cent of the original volume of ordinary serum refined or the possible yield of ordinary serum obtainable under these regulations from the hyperimmune blood used.

(*b*) When concentrated clear serum is prepared, the completed product shall contain not less than 80 per cent of true serum and represent not more than 78 per cent of the original volume of ordinary serum refined, or the possible yield of ordinary serum obtainable under these regulations from the hyperimmune blood used.

(*c*) When whole blood is clarified, 3 per cent shall be allowed for fibrin contained therein when calculating the possible yield of ordinary serum.

(*d*) Unconcentrated clear serum shall be tested as prescribed in sections 4 and 5 of this regulation and the immediate or true containers thereof bear recommendations for minimum doses prescribed in paragraph 1, section 6, hereof.

(*e*) Concentrated clear serum shall be tested as prescribed in sections 4 and 5 of this regulation except that if it is desired to market the product in doses smaller than those indicated in paragraph 1, section 6, of this regulation, the pigs in the test shall receive 1.5 cubic centimeters of the product to be tested.

Paragraph 3. Ordinary defibrinated blood anti-hog-cholera serum which has been found "Unsatisfactory for potency" or "Unsatisfactory for purity," or which is derived from tuberculous hogs, may be refined and concentrated by licensed establishments in accordance with methods approved by the chief of bureau, provided solutions other than those necessary and permitted in the refinement of the product are not added to serum previously found "Unsatisfactory for potency." The completed product shall be tested as provided in sections 4 and 5 of this regulation and when derived from tuberculous hogs shall be heated as prescribed in paragraph 11, section 2, of this regulation, or tested on guinea pigs, as approved by the chief of bureau. The immediate or true containers of the product shall bear a minimum dosage table applicable under the provisions of this regulation except that serum which before refinement and concentration was declared "Unsatisfactory for potency" shall bear a dosage table only in accord with the terms of paragraph 1, section 6, hereof.

Paragraph 4. Should the tests required by this regulation be found "Satisfactory for potency" and "Satisfactory for purity," as defined in rules B and E hereof, and the test pigs receive doses of the serum as prescribed in subdivision (*e*), paragraph 2, of this section, the product may be marketed if it is recommended for use in doses not less than those appearing in the following table. This table shall be a part of trade labels, wrappers, and the like, affixed to or used in connection with each immediate or true container of the product:

Weight.	Minimum dose.
Sucking pigs	15 c. c.
Pigs 20 to 40 pounds	25 c. c.
Pigs 40 to 90 pounds	30 c. c.
Pigs 90 to 120 pounds	35 c. c.
Hogs 120 to 150 pounds	45 c. c.
Hogs 150 to 180 pounds	50 c. c.
Hogs 180 pounds and over	60 c. c.

SECTION 11. *Paragraph 1.* Each immediate or true container of anti-hog-cholera serum which has been tested and not found to be worthless, contaminated, dangerous, or harmful may bear over the opening of its neck a paper cap attached by the establishment and on which may appear the words "U. S. Released." Whenever caps bearing the aforesaid words are applied they shall be serially numbered and bear the license legend of the establishment properly separated from the words and number aforesaid. It shall be affixed only after approval thereof by the bureau and under the supervision of a bureau employee. When these caps are not in use as described they shall be held under bureau lock. Strong, flexible bands, perforated as hereinafter described, shall be used to hold the aforesaid caps securely over the openings of the containers of the product. All perforations of said bands shall consist of the number of the license under which the product is produced; a number assigned to the batch to which the perforated band is affixed; and the last figure in the number used for indicating the calendar year. The perforating machine, when not in use for perforating bands as aforesaid, shall be held under bureau lock.

Paragraph 2. The return date placed upon trade labels of anti-hog-cholera serum shall be a date not more than two years after the date of bleeding. The date of bleeding shall be regarded as the date upon which the first serum was collected, which is a part of the batch.

Paragraph 3. Should the return date of any batch of anti-hog-cholera serum expire before the serum is used, the serum should be retested, and if found "Satisfactory for potency" and "Satisfactory for purity," as defined in rules B and E hereof, the return date may be extended for one year from the date of conclusion of the retest for potency.

Paragraph 4. Should a batch of anti-hog-cholera serum not be found "Satisfactory for potency" or "Satisfactory for purity" before the expiration of two years from the date of collection of the oldest serum in the batch, or not in time to allow it to be used before the expiration of two years, the return date will be limited to six months from the date of conclusion of a satisfactory test for potency.

Paragraph 5. Trade labels affixed to or used in connection with the immediate or true containers of anti-hog-cholera serum shall plainly show the quantity of the contents of said containers.

Paragraph 6. No immediate or true container of anti-hog-cholera serum shall be filled in whole or in part, and no trade label shall be affixed to such containers, except under the supervision of a bureau employee.

Paragraph 7. Anti-hog-cholera serum shall not be removed from the premises of a licensed establishment unless it has been prepared in accordance with the provisions of these regulations.

Paragraph 8. No anti-hog-cholera serum shall be released for marketing unless and until all the information required by these regulations has been affixed to the containers thereof under the supervision of a bureau employee.

SECTION 12. The following special facilities and such others as may be required by the chief of bureau shall be provided by each establishment licensed to prepare anti-hog-cholera serum.

(*a*) Separate operating rooms.

(*b*) A separate room in which the hog shall be washed, cleaned, and otherwise prepared before being taken into the operating room.

(*c*) A separate room for conducting autopsies.

(*d*) A separate room for the preparation and mixing of serum.

(*e*) A separate room for washing and sterilizing equipment.

(*f*) Clean cloths, which shall be kept damp when in use, to be used for covering hogs during all operations incident to the collection of anti-hog-cholera serum.

(*g*) All outside doors, windows, or other openings shall be equipped with dust screens.

SECTION 13. All persons immediately before entering the operating or laboratory rooms of an establishment licensed to prepare anti-hog-cholera serum when these rooms are in use shall change their outer clothing or effectively cover the same by the use of gowns or other satisfactory garments.

REGULATION 20.—BACTERINS, VACCINES, TOXINS, ETC.

SECTION 1. *Paragraph 1.* Viruses entering into the preparation of bacterins, vaccines, or toxins shall be derived from animals which are affected with no disease other than that for which the bacterins, vaccines, or toxins are intended to be used.

Paragraph 2. All bacterins, vaccines, and toxins shall be derived from the specific cause of the diseases for which they are intended to be used or from the secondary invaders of the respective diseases.

SECTION 2. *Paragraph 1.* The return date on the trade labels of blackleg vaccine prepared from attenuated *Bacillus chauveaui*, or blackleg muscle virus, shall be a date not more than one and one-half years later than the date on which the preparation of the product is completed, without regard to the filling of final containers.

Paragraph 2. The return date on the trade labels of anthrax vaccine prepared by the Pasteur method shall be a date not more than three months later than that on which the preparation of the product is completed without regard to the filling of final containers.

Paragraph 3. Trade labels affixed to or used in connection with the immediate or true containers of tuberculin shall bear a statement indicating the equivalent of Koch's old tuberculin (K. O. T.) contained in each cubic centimeter, disk, etc., of the product as marketed. Such labels shall also bear recommendations regarding the minimum dose to be administered, and this dose for subcutaneous use shall be not less than the equivalent of 0.5 gram of Koch's old tuberculin. Tuberculin intended for subcutaneous, intracutaneous, or cutaneous use shall be filtered through germ-proof filters before being marketed.

SECTION 3. The immunity unit for measuring the strength of tetanus antitoxin shall be 10 times the least quantity of antitetanic

serum necessary to save the life of a 350-gram guinea pig for 96 hours against the official-test dose of the standard toxin furnished by the Hygienic Laboratory of the United States Public Health Service. The number of the immunity units recommended for the prevention of tetanus in a horse shall be at least 500 units.

REGULATION 21.—ADMISSION OF VIRUSES, SERUMS, TOXINS, AND ANALOGOUS PRODUCTS.

SECTION 1. *Paragraph 1.* No virus, serum, toxin, or analogous product which has not been prepared, handled, stored, and marketed in accordance with these regulations, and no virus, serum, toxin, or analogous product which is worthless, contaminated, dangerous, or harmful shall be brought on to the premises of any licensed establishment.

Paragraph 2. Hog-cholera virus and anti-hog-cholera serum prepared by the Bureau of Animal Industry will be admitted to licensed establishments for use as prescribed in these regulations or as may be approved by the chief of bureau.

Paragraph 3. Hog-cholera virus procured from outbreaks of hog cholera on farms that are free from other communicable diseases will be admitted to licensed establishments when desired for use in propagating a new strain to be used in inoculating virus. Before such virus is used in the production of simultaneous virus or hyperimmunizing virus, however, pigs weighing from 30 to 80 pounds shall be inoculated therewith with the view of determining whether the purity and virulence of the product are satisfactory. The virus should be passed through pigs as described until its virulence and purity are satisfactory or the product should be destroyed.

Paragraph 4. Anti-hog-cholera serum and hog-cholera virus collected by licensed establishments and suitable for use under these regulations may be transported from one licensed establishment to another or between units of the same establishment provided these products are properly packed. If said products are not completed and labeled as prescribed by these regulations they shall be so packed or iced that a temperature of not more than 55° F. will be maintained therein during transportation and the containers thereof shall be sealed by a bureau employee, this seal to be broken by such an employee at the point of destination.

THE VIRUS-SERUM-TOXIN LAW.

[Extract from "An act making appropriations for the Department of Agriculture for the fiscal year ending June thirtieth, nineteen hundred and fourteen," approved March 4, 1913 (37 Stat., 832).]

That from and after July first, nineteen hundred and thirteen, it shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or

analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized. That the importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are hereby prohibited. The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products; for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer. That the Secretary of Agriculture be, and hereby is, authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid. The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful. All licenses issued under authority of this Act to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of this Act, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals. That any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment licensed under this Act where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid. That any person, firm, or corporation who shall violate any of the provisions of this Act shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

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